DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 7, 2014

Limacorporate S.p.A
% Dr. Stephen J. Peoples, VMD, MS
Principal Consultant
Peoples & Associates Consulting, LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K142139
Trade/Device Name: SMR 40mm Glenosphere
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: October 21, 2014
Received: October 24, 2014

Dear Dr. Peoples:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K142139
Device Name: SMR 40mm Glenosphere
Indications for Use:

SMR 40mm Glenosphere
Indications for Use

The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.
The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant;
- cuff tear arthropathy (CTA Heads only).

The Large Resection Stems (**not available in the US**) are indicated for oncology applications.

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.

The Anatomic glenoid construct consists of an all polyethylene glenoid or a metal back assembled with a liner while the Reverse glenoid construct consists of the metal back, the connector and the glenosphere. On the glenoid side, the fixation of the all polyethylene glenoid or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	Use		Available in US	Available in Canada
A	R			Cem	Not Cem		
●	●	SMR Stems (Cemented, Cemented Revision)	Ti6Al4V	X		●	●
●	●	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X	●	●
●	●	SMR Large Resection stems	Ti6Al4V	X			●
●	●	SMR Modular Augments	Ti6Al4V	X			●
●		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X	●	●
	●	SMR Reverse Humeral Body	Ti6Al4V	X	X	●	●
	●	SMR Reverse HA Coated Humeral Body	Ti6Al4V+HA		X		●
●	●	Humeral Extension	Ti6Al4V	X	X	●	●
●		SMR Humeral Heads (Standard, CTA)	CoCrMo	X	X	●	●
			Ti6Al4V	X	X		●
●		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X	●	●
●		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X	●	●
	●	SMR Glenospheres	CoCrMo		X	●	●
			Ti6Al4V		X		●
			UHMWPE X-Lima +Ti6Al4V		X		
	●	SMR Connectors	Ti6Al4V		X	●	●
	●	Reverse Liners	UHMWPE	X	X	●	●
			UHMWPE X-Lima	X	X		
			CoCrMo	X	X		
			Alumina	X	X		
●		SMR Cemented Glenoids	UHMWPE	X		●	●
●		SMR 3 Pegs Cemented Glenoids	UHMWPE X-Lima	X			
			UHMWPE	X		●	
●	●	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*	●	●
			Ti6Al4V+PoroTi+HA		X		●
●	●	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*		
●	●	SMR TT Metal Back Peg	Ti6Al4V	X	X		
●		SMR Metal Back Liner	UHMWPE	X*	X*	●	●
			UHMWPE X-Lima		X		
● *	●	SMR Bone screws	Ti6Al4V		X	●	●
	●	SMR Glenoid Plates	Ti		X		
Material Standards							
Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **Ti** (ASTM F67) - **UHMWPE** (ISO 5834-2 - ASTM F648) **Alumina** (ISO 6474) – **PoroTi Titanium Coating** (ASTM F1580) – **HA Hyroxyapatite Coating** (ISO 13779)							

A= Anatomic / R=Reverse

***NOTE :**

- **In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.**
- **Outside the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for uncemented use with the addition of screws for fixation.**
- **The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **The SMR TT Metal Back is indicated for primary implant in anatomic or reverse total shoulder arthroplasty with poor glenoid bone quality or in revision case with consistent bone loss on the**

glenoid side. The implant is suitable for implantation with or without bone graft. These indications are not yet approved in the US.

In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date: July 23, 2014

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Dr. Stephen J. Peoples
Principal Consultant
Phone: 260-645-0327
FAX: +39 0432945512

Product	Common Name	Product Code	Regulation and Classification Name
SMR 40mm Glenosphere	Shoulder Prosthesis	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
		PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR 40mm Glenosphere is a Co-Cr-Mo glenosphere intended to be used with the 40mm standard UHMWPE reverse liner (standard or retentive) as part of the SMR Reverse Shoulder System (K110598). The SMR Reverse Shoulder System consists of a humeral stem, a reverse humeral body, a reverse liner, a metal-back glenoid, a glenosphere and a connector with screw. Bone screws are used for the fixation of the metal-back glenoid to the scapula. Humeral stems are provided for both cemented and cementless (K100858, K101263, K111212, K113523) fixation as well as reverse humeral bodies (K110598). The SMR Reverse Shoulder System metal back glenoids (K110598, K113254 and K133349) and glenospheres (K110598) are intended for uncemented press-fit use only with the addition of screws for fixation.

SMR 40mm Glenosphere is made of CoCrMo alloy that conforms to ASTM F1537 – ISO 5832-12 in two (2) different designs: a standard glenosphere that can be centered with respect to the glenoid component or eccentrical glenosphere that provides offset. Both designs have a spherical shape of 40mm diameter and articulate with the standard 40mm ultra-high molecular weight polyethylene (ASTM F648 – ISO 5834-2) liners that are coupled to the humeral body. Two designs for the 40mm liners are available: standard and retentive.

The 40mm glenospheres are coupled to a SMR metal-back glenoid (K113254, K133349) through a double male taper, one side of which is connected to the glenosphere while the

other is coupled with the glenoid component. To increase the solidity of the system, a screw is used to link the glenosphere to the glenoid component. The screw is inserted through a hole on the surface of the glenosphere, passing through the internal cavity of the connector and then screwed to the metal-back.

The SMR 40mm Liners are made from standard ultra-high molecular weight polyethylene conforming to ASTM F648 – ISO 5834-2. They are coupled to the SMR Reverse Humeral Bodies (K110598) via a taper. The liners are designed with a bevel cut in their inferior aspect to reduce the possibility of accidental contact between the polyethylene liner and the scapular bone during adduction – abduction movements. The 40mm liners are available in standard and retentive designs in three (3) thicknesses (STD, +3mm and +6mm) with the retentive liners characterized by a deeper spherical concavity than is present in the standard liners.

Intended Use / Indications for Use:

The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.

The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
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The Anatomic glenoid construct consists of an all polyethylene glenoid or a metal back assembled with a liner while the Reverse glenoid construct consists of the metal back, the connector and the glenosphere. On the glenoid side, the fixation of the all polyethylene glenoid or the metal back determines if the construct is cemented or uncemented.

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A	R			Cem	Not Cem		
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●	●	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X	●	●
●	●	SMR Large Resection stems	Ti6Al4V	X			●
●	●	SMR Modular Augments	Ti6Al4V	X			●
●		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X	●	●
	●	SMR Reverse Humeral Body	Ti6Al4V	X	X	●	●
	●	SMR Reverse HA Coated Humeral Body	Ti6Al4V+HA		X		●
●	●	Humeral Extension	Ti6Al4V	X	X	●	●
●		SMR Humeral Heads (Standard, CTA)	CoCrMo	X	X	●	●
			Ti6Al4V	X	X		●
●		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X	●	●
●		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X	●	●
	●	SMR Glenospheres	CoCrMo		X	●	●
			Ti6Al4V		X		●
			UHMWPE X-Lima +Ti6Al4V		X		
	●	SMR Connectors	Ti6Al4V		X	●	●
	●	Reverse Liners	UHMWPE	X	X	●	●
			UHMWPE X-Lima	X	X		
			CoCrMo	X	X		
			Alumina	X	X		
●		SMR Cemented Glenoids	UHMWPE	X		●	●
●		SMR 3 Pegs Cemented Glenoids	UHMWPE X-Lima	X			
			UHMWPE	X		●	
●	●	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*	●	●
			Ti6Al4V+PoroTi+HA		X		●
●	●	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*		
●	●	SMR TT Metal Back Peg	Ti6Al4V	X	X		
●		SMR Metal Back Liner	UHMWPE	X*	X*	●	●
			UHMWPE X-Lima		X		
● *	●	SMR Bone screws	Ti6Al4V		X	●	●
	●	SMR Glenoid Plates	Ti		X		

Material Standards

Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **Ti** (ASTM F67) - **UHMWPE** (ISO 5834-2 - ASTM F648)
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Predicate Devices:

- SMR Reverse Shoulder System (Limacorporate, K110598);
- Promos Reverse Shoulder System (Plus Orthopedics, K081016);
- Inverse/reverse Shoulder (Zimmer, K053274);
- Delta Xtend Reverse Shoulder (DePuy, K091751).

Comparable Features to Predicate Device(s):

The SMR 40mm Glenosphere and Liner are similar to the predicate devices in terms of intended use, indications, design and materials. The SMR 40mm Glenosphere and the predicates are all intended for total primary or revision reverse shoulder joint replacement. All systems are provided with reverse liners and glenospheres of similar diameters that are intended to articulate together. In all the systems, the glenospheres are fixed to the glenoid bone through the use of a glenoid component and connector.

The components of the SMR 40mm Glenosphere and Liner are manufactured from the same or similar materials as the predicate devices.

Non-Clinical Testing:

The SMR 40mm Glenosphere was tested for fatigue resistance of the modular connection to the metal-back glenoid component. Mechanical testing was performed on worst case components or constructs. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR 40mm Glenosphere to the predicate devices.